## REMARKS

Claims 1-16 and 18-26 are canceled, claim 17 is withdrawn from examination, and new claims 27-32 are added. Support for the new claims can be found throughout the specification, particularly in the examples, and the new claims do not introduce new matter.

Objection to the abstract

Examiner has objected to the abstract for using the terms "comprising," "said," and "comprises." Applicant has made proper corrections to remove those terms from the abstract. Therefore, the objection is overcome.

Objection to the claims

Examiner has objected claims 11, 19, 22 and 24. As these claims are canceled, the objection is rendered moot.

Rejections to the claims

Examiner has rejected claims 1-16 and 19-26 under 35 U.S.C. §112, second paragraph. As these claims are canceled, the rejection is rendered moot.

Examiner has rejected claims 1-16 and 19-26 under 35 U.S.C. §102(e) as being anticipated by Tanizawa et al. (US2004/0018235). As these claims are canceled, the rejection is rendered moot.

Examiner has rejected claims 1-5, 9, 11-14, 19-21 and 23-26 under 35 U.S.C. §102(e) as being anticipated by Tillyer et al. (US2003/0211151). As these claims are canceled, the rejection is rendered moot.

Examiner has rejected claims 1-14, 16 and 19-26 under 35 U.S.C. §103(a) as being obvious over Alberts et al. (EP0465096). As these claims are canceled, the rejection is rendered moot.

Patentability of new claims 27-32

Claims 27-32 are directed to a sustained release composition of pitavastatin. The composition comprises an inner phase and an outer phase. An inner phase comprises

pitavastatin as active ingredient, and microcrystalline cellulose and stabilizer as excipients. The outerphase requires matrix former and flow agent. A weight percentage or percentage range for each component is specified in the claims.

Tanizawa et al. teach a controlled release composition containing pitavastatin with two layers. However, Tanizawa et al. fail to teach microcrystalline cellulose (MCC) at the inner phase, nor the specific weight percentage range of MCC. Tanizawa et al. teach HPMC as excipient attributed to the function of controlled release at the outer phase of the composition. However, the weight percentages of HPMC at the outer phase have been <10% throughout the disclosure. Furthermore, Tanizawa et al. do not teach, suggest or inspire one of skilled in the art to include more than 10% HMPC into the outer phase of the composition. Accordingly, Tanizawa et al. fail to teach every element of the claimed invention, and would not anticipate the claims, Tanizawa et al. also fail to make the claimed invention obvious.

Tillyer et al. teach a delayed release composition of statins particularly simvastatin comprising the statins and enteric coating layer. On paragraph 43 ({0043]) and claim 40. Tillyer et al. teache the delayed composition to comprise simvastain as active agent, a sub-coat (inner phase) containing a mixture of 50% hydroxypropyl cellulose/50% hydroxypropyl methyl cellulose, and a polymeric coat which does not contain HMPC. Therefore, Tillyer et al. fails to teach a sustained release composition of pitavastatin containing HMPC at the outer phase. Tillyer et al. further fails to teach microcrystalline cellulose at inner phase (sub-coate in the reference). Accordingly, Tillyer et al. fails to anticipate the claimed invention.

Alberts et al. teach a time-controlled composition of simvastatin comprising two layer in the composition. The inner layer contains about 5% by weight microcrystalline cellulose (MCC), and the outer layer contains about 0.5% HMPC. Therefore, Alberts et al. fails to teach the claimed pitavastatin composition with the specified weight percentage (20-50%) MCC at the inner phase and (15-40%) HMPC at the outer phase. Furthermore, nowhere in the disclosure of Alberts et al., the reference suggests or implies replacing simvastatin with pitavastatin, nor do Alberts et al. give any reason for one of skilled in the art to modify the Alberts et al. teachings to the particular weight percentages of the excipients as claimed in the present application. Therefore, The claimed invention is patentable over Alberts et al.

In view of the above, applicant submits that all issues raised in the Office Action have been addressed herein. Applicant respectfully requests withdrawal of the objections and rejections.

Respectfully submitted,

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